Attorney's Docket No.: 00633-025001 / 99/022A

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3738

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Saumil N. Merchant et al.	Art Unit	: 3738
Serial No.	: 09/625,644	Examiner	: D. Isabella
Filed	: July 26, 2000		
Title	: MIDDLE-EAR IMPLANT		

JSW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INTERVIEW SUMMARY AND RETRANSMISSION OF APPEAL BRIEF

In response to the telephone call from the Examiner on July 14, 2004 reporting that an appendix of claims had not been received, Applicant encloses herewith an appeal brief and an appendix of claims. Consistent with Rule 1.192(a), the brief and the accompanying appendix are filed in triplicate.

A fee accompanying the appeal brief was submitted on May 19, 2003. Accordingly, no additional fees are believed to be due in connection with the filing of this response. However, to the extent fees are due, or if a refund is forthcoming, please adjust our deposit account 06-1050, referencing attorney docket "00633-025001."

Respectfully submitted,

Date: July 14, 2004

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Mail Stop Appeal Brief - Patents
Commissioner for Patents
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BRIEF ON APPEAL

Applicant appeals the final rejection of claims 1-26 in the final action dated November 18, 2002. A notice of appeal was filed on February 19, 2003.

Applicant requests that the rejection of claims 1-26 be reversed.

(1) REAL PARTY IN INTEREST

The real party in interest is the Massachusetts Eye and Ear Infirmary, a Massachusetts corporation having a place of business at 243 Charles Street, Boston, Massachusetts, as evidenced by an assignment executed July 24, 2000 and submitted for recordation at the U.S. Patent Office on July 26, 2000. The assignment was recorded at reel 01097 frame 0540 on July 26, 2000.

(2) RELATED APPEALS AND INTERFERENCES

Neither Applicant, nor Applicant's legal representative, nor the assignee are aware of any appeals or interferences that will directly affect or be affected by or have a bearing on the Board's decision in the pending appeal.

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Irja Zarembok
Typed or Printed Name of Person Signing Certificate

appeals or interferences that will directly affect or be affected by or have a bearing on the Board's decision in the pending appeal.

(3) STATUS OF CLAIMS

Applicant filed the present application on July 26, 2000 with claims 1-26. Of these, claims 1, 21 and 22 are independent.

Claims 1-26 were initially rejected on the basis of double-patenting over the issued parent of this application. The rejection was subsequently overcome and claims 1-26 were allowed on April 8, 2002.

On May 30, 2002, the notice of allowance was vacated and claims 1, 3-20 and 22-26 were rejected as being anticipated by *Nadol*. Claims 2 and 21 were rejected as being rendered obvious by *Nadol*.

Claim 2 also stands rejected under 35 USC 112. In a final office action.

Claims 1-26 also stand rejected under the judicially-created doctrine of obviousness type double patenting over U.S. 6,251,138, which is the parent of the present application.

On February 19, 2003, Applicant appealed from the rejection. A copy of the claims pending in this appeal is attached as Appendix I.

No claims have been cancelled. Accordingly, claims 1-26 are pending and on appeal.

(4) STATUS OF AMENDMENTS

On January 21, 2003, following the final rejection, Applicant filed a request for reconsideration. The request for reconsideration proposed an amendment to claim 2 to address the rejection under section 112. In an advisory action mailed on February 26, 2003, the Examiner maintained his rejection of the claims and declined to enter the proposed amendment.

Applicant last amended the claims in a response to the non-final office action of May 30, 2002. These amendments have been entered. The only claims amended during prosecution have been claims 1, 2, 21, and 22.

(5) SUMMARY OF INVENTION

Applicant has recognized that the ability of a middle-ear balloon implant to transmit sound depends on a combination of factors that include: the material from which the balloon is made, the shape and size of the balloon, the fluid contained within the balloon, and the extent to which that fluid is pressurized. The combined effect of these, and perhaps other factors yet to be discovered, can be viewed as an "equivalent volume" of the balloon. The representation of the complex interplay of these disparate physical parameters in a single quantity appears to be unrecognized in the art of middle-ear balloon design.

Applicant's invention is an implant for implantation in a middle-ear chamber. The implant includes a pliant membrane formed into a balloon. The balloon is configured to fit within the middle-ear chamber and to contact an eardrum. The pliant membrane forms a balloon having an equivalent volume that is selected to permit the eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.[1]

In another aspect, applicant's invention includes an implant, for implantation in a middle-ear chamber. The implant has a plurality of balloons, each of which is formed from a pliant membrane. The balloons are configured to fit within the middle-ear chamber with at least one of the balloons at least partially in contact with the eardrum. Each balloon has an equivalent volume selected to permit the eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.[2]

In another aspect, the invention includes a surgical method for treating middle-ear hearing loss of a patient, by positioning a balloon in the patient's middle ear at least partially in contact with the eardrum. The synthetic balloon is formed of a thin pliant membrane of biocompatible material such that the balloon has an equivalent volume high enough to permit sound-induced motions of the eardrum, ossicles, and the round window membrane to an extent

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[1] See specification from page 2, line 27 to page 3, line 3, from page 6, line 9 to page 7, line 24, and at page 13, lines 1-6; see also specification FIG. 3 and FIGS. 4A-C.

[2] See specification at page 3, lines 20-25, page 11, lines 10-23, and at page 15, lines 6-11; see also FIG. 5 of specification.

that permits the perception of sound by the patient. The pliant membrane is also substantially impermeable to water and to gases during extended contact with body tissues.[3]

Applicant does not claim "equivalent volume" per se. What Applicant claims is a balloon that has, as a structural limitation, an equivalent volume that permits the eardrum to respond to incident acoustic waves well enough to permit perception of sound.

(6) ISSUES

At issue in this appeal are:

1. Whether claims 1, 3-20, 21, and 22-26 are unpatentable under 35 USC 102 in view of *Nadol*.

2. Whether the obviousness double-patenting rejection of claims 1-26 is proper in view of the terminal disclaimer.

3. Whether claim 21 is rendered obvious by *Nadol*.

4. Whether claim 2 is rendered obvious by *Nadol*.

5. Whether claim 2 is indefinite.

(7) GROUPING OF CLAIMS

Group I: Independent claims 1 and 21, and dependent claims 3-20.

Group II: Independent claim 22 and dependent claims 23-26.

Group III: Dependent claim 2.

Claims 1 and 3-21 stand or fall together. Claim 2 stands or falls on its own. Claims 22-26 stand or fall together.

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[3] See specification at page 4, lines 4-10, page 12, lines 4-14, and page 15, lines 12-20.

(8) ARGUMENT

Double Patenting Rejection

Claims 1-26 stand rejected for obviousness-type double-patenting over U.S. Patent 6,251,138, which is the parent of the pending application. In a response to the office action of May 30, 2002, in which the Examiner issued the present double-patenting rejection, Applicant submitted a terminal disclaimer.

In view of the terminal disclaimer, Applicant requests withdrawal of this double-patenting rejection.

Section 112 rejection of claim 2

Claim 2 stands rejected as allegedly being indefinite for failure to particularly point out the subject matter of the invention. In particular, the Examiner states that there is no support for "its [physical] volume."

In response to the final office action, Applicant proposed a formal amendment that would have addressed this issue. However, the Examiner declined to enter this amendment because it allegedly did not place the application in better condition for appeal.

Even in the absence of this amendment, Applicant submits that claim 2 satisfies 35 USC 112. The standard for determining whether a claim is indefinite is

> "whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification."[4]

The exact term "physical volume" is not used in the specification. However, Applicant does use the term "actual volume" to distinguish the volume of the balloon, as one would physically measure it, from the equivalent volume, which is measured in terms of the balloon's ability to transmit sound.[5] Hence, the notion of two different types of "volume" is clearly set forth in the specification.

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[4] *North American Vaccine, Inc. v. American Cyanimid*, 7 F. 3d 1571 (CAFC 1993), cert. denied 511 U.S. 1069 (1993)

[5] See specification at page 7, lines 19-21 ("Throughout this specification, the equivalent volume is expressed in terms of a percentage of the balloon's actual volume.")

Applicant submits that one of ordinary skill, after having read the specification, would recognize the existence of two kinds of "volume," namely "equivalent volume" and "actual volume." That person would then recognize that "physical volume" in claim 2 must correspond to the "actual volume," since no other type of volume is discussed in the specification. This recognition is reinforced by the adjective "physical," which suggests the volume obtained from a physical measurement, i.e. an "actual" volume.

Since one of ordinary skill would have no difficulty ascertaining the scope of claim 2, Applicant requests that the rejection of claim 2 under 35 USC 112 be reversed.

Section 103 rejection of claim 2

The Examiner asserts that claim 2 is rendered obvious by *Nadol*.

The final office action suggests that there is some confusion concerning "what value defines an acoustic impedance corresponding to the equivalent volume." An explanation can be found in the specification beginning on the last paragraph of page 7. This explanation is summarized as follows:

A 21 microliter air bubble will have some acoustic impedance. Similarly, a 30 microliter balloon will also have an acoustic impedance. If these two acoustic impedances are the same, then, since 21 microliters is 70% of 30 microliters, we say that the balloon has an acoustic impedance equivalent to 70% of its physical volume. Such a balloon would be within the scope of the claim. A 30 microliter balloon whose equivalent impedance is that of a 1 microliter air bubble, for example, would lie outside the scope of the claim.

According to the Examiner, *Nadol* renders claim 2 obvious The Examiner does not, however, indicate where *Nadol* teaches or suggests the balloon recited in claim 2. After careful scrutiny of *Nadol*, Applicant has been unable to identify any teaching or suggestion of "a balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of its physical volume." In fact, Applicant has been unable to find any mention of "equivalent volume" whatsoever in *Nadol*.

To establish a prima facie case of obviousness, the Examiner must, among other things, set forth the differences between the prior art and the claims at issue.[6] In the case of claim 1, the Examiner has failed to do this. All the Examiner has done is make the conclusory assertion:

"[i]t appears that Nadol (138) has an equivalent volume of at least 70%."

Such an assertion, completely devoid of support from the cited reference, does not rise to the level of a prima facie case of obviousness. Accordingly, Applicant requests that the section 103 rejection of claim 2 be reversed.

Section 102(b) rejection based on Nadol

Claims 1 and 22 stand rejected as being anticipated by *Nadol*.[7] In support of this rejection, the Examiner draws attention to a passage in *Nadol* that states:

> "[i]n a preferred embodiment, the bubble is formed of a thin pliant material effective to achieve a good impedance match between the tympanum and the round window"[8]

Although this passage does not refer expressly to "equivalent volume," there is a relationship between equivalent volume and acoustic impedance. As best understood, the Examiner concludes from this that a balloon that is impedance matched to the tympanum and round window *necessarily* has an equivalent volume consistent with the limitation recited in claim 1. From this, the Examiner concludes that *Nadol* discloses the claimed balloon.

The Examiner appears to assume that by simply implanting a balloon whose impedance matches that of the tympanum and round window, one can restore hearing in a patient having a fluid-filled middle ear.

In making this assumption, the Examiner is merely repeating the same conceptual mistake that Applicant himself made at one time. Had the Examiner subjected his assumption to experimentation, he may have realized, as has the Applicant, that the assumption is incorrect. Indeed, the Examiner's reluctance to concede possible error in this assumption is a testament

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[6] *Graham v. John Deere*, 383 U.S. 1 (1966) ("Under sec. 103, the scope and content of the prior art are to be determined, difference between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.").

[7] *Nadol, Jr.*, U.S. Patent 5,480,433 and U.S. Patent 5,356,430.

[8] *Nadol*, col. 1. line 49-52.

both to the non-obviousness of the claimed invention and to the continuing usefulness of the scientific method.

Like so many assumptions that at one time seemed reasonable, this one has been experimentally disproven. In a declaration filed in response to the first office action, Dr. Nadol refers to actual tests involving the balloon described in the *Nadol* patent. The record does not indicate that the Examiner ever considered this declaration.[9] Had he done so, he would have learned that in clinical trials, the *Nadol* balloon simply did not function consistently with the foregoing assumption.

All the cited passage manages to achieve is to disclose that there are balloons in existence whose impedance was selected to match the impedance of the tympanum and the round window. This is neither the same as nor suggestive of what is recited in the independent claims. In fact, the clinical trials referred to in the declaration provide experimental proof that a balloon whose impedance matches the tympanum and round window does not necessarily have

> "an equivalent volume selected to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound"

as recited in claim 1. Indeed, were this the case, the clinical trials would have shown more promising results.

In the final office action, the Examiner also states that *Nadol* teaches a balloon in which

> "the materials for the membrane are selected for good acoustic transmission."

As a threshold matter, it is unclear why such a teaching would be relevant to the claims in the first place. Claim 1 does not recite a balloon made of "a material selected for good acoustic transmission." Claim 1 recites a balloon having a particular *equivalent volume*. Although the flexibility of the balloon's wall plays some role in determining equivalent volume, it is by no means the only factor. For example, it is quite possible to select a material for good acoustic transmission but to nevertheless degrade the balloon's equivalent volume in other ways, for

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9 MPEP 716.01 "All declarations...traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action."

example, by placing seams that interfere with acoustic transmission, or filling the balloon with a gas with poor acoustic characteristics.

Nadol expressly teaches four criteria for constructing a balloon:

> "[F]our primary criteria are believed to be desirable. The balloon must be able to flex with both pressure changes and sound vibrations, must be of low permeability to gases, must be stable and non-toxic to the biological environment of the middle ear, and must be easily formed into the desired balloon shape."[10]

Had *Nadol* recognized the significance of equivalent volume, one might expect to have seen it mentioned in the foregoing passage. However, there is no discussion, or even mention of equivalent volume, either in the foregoing passage or anywhere else in *Nadol*. While it is true that flexibility is one contributor to equivalent volume, it is apparent from the following passage that *Nadol* lacks any disclosure of either a connection between flexibility and equivalent volume or any meaningful way to determine an appropriate flexibility:

> "The amount of flexibility which is necessary for good compressive response of a membrane and the balloon interior is unknown, and is difficult to quantify. When compared to air, the presence of any material in the middle ear will almost certainly reduce the level of sound perception by the inner ear. However, in comparison to the fluid found in a congested middle ear, a flexible compressible object with a thin balloon membrane should improve hearing. Therefore, the optimal amount of stiffness allowed in the balloon membrane must ultimately be determined by clinical observation."[11]

A proper rejection under 35 USC 102 requires that the reference disclose every element of the claimed invention.[12] The Examiner has not identified any such disclosure. Instead, the Examiner states that *Nadol*'s "basic tenet" involves providing pliant balloons for acoustic transmission.

Applicant is not seeking to patent a "tenet," either basic or otherwise. Applicant seeks to patent a *structure*, the limitations of which are recited in the claims. A proper rejection under

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10 *Nadol*, col. 3, lines 5-10.

11 *Nadol*, col. 4, lines 11-21.

12 *Hybritech v. Monoclonal Antibodies*, 802 F.2d 775 (CAFC 1985) ("It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention"); *Akzo v. U.S. Int'l Trade Commission* 802 F.2d 1471 ("Under 35 USC 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference"); *Titanium Metals v. Banner*, 778 F.2d 775 (CAFC 1985) ("Anticipation under section 102 can be found only if a reference shows exactly what is claimed").

section 102 requires that each and every limitation of the claimed structure be taught by the reference.

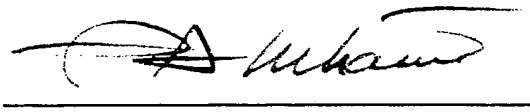
Almost by definition, any prior art reference would have the same "basic tenet" as an application under examination. Applicant is unaware of any requirement that patentability be predicated on a difference in "tenet" between the claimed invention and the prior art. Indeed, were the patent law consistent with the Examiner's position, *Nadol* would foreclose the patenting of any further improvement whatsoever in middle-ear balloon implants.

Despite having repeatedly cited *Nadol*, the Examiner has never identified specific passages in *Nadol* that teach the claim limitations. Instead, all the Examiner has done is to observe that both Applicant and *Nadol* teach implanting balloons in the middle ear. This is insufficient as a matter of law to maintain a rejection under section 102(b). Accordingly, Applicant requests that the rejection of claims 1 and 22 under section 102(b) be reversed.

Applicant encloses a $320 check in payment for the fee associated with filing of an appeal brief. No additional fees are believed to be due in connection with the filing of this appeal brief. However to the extent that additional fees are due, or if a refund is forthcoming, please adjust our deposit account 06-1050.

Respectfully submitted,

Date: 3/18/04



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Appendix of Claims

CLAIMS PENDING ON APPEAL

1. **(Amended)** An implant for implantation in a middle-ear chamber, said implant comprising:

a pliant membrane formed into a balloon, said balloon configured to fit within said middle-ear chamber and to contact an eardrum, said pliant membrane forming a balloon having an equivalent volume selected to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.

2. **(Amended)** The implant of claim **1**, wherein said pliant membrane forms a balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of its physical volume.

3. **(Original)** The implant of claim **1**, wherein said implant further comprises a tab extending from an end of said balloon.

4. **(Original)** The implant of claim **3** wherein said tab includes a radio-opaque marker.

5. **(Original)** The implant of claim **1**, wherein said balloon is an ovaloid having a maximum dimension along a principal axis extending between a first end and a second end, and said implant further comprises a tab extending from at least one of said first and second ends.

6. **(Original)** The implant of claim **5**, wherein said balloon is dimensioned to be positioned by surrounding structures within said middle-ear chamber and to displace fluid and soft tissue therefrom, thereby forming a compliant cushion presenting low acoustic impedance to motion of said eardrum.

7. **(Original)** The implant of claim **1**, wherein said pliant membrane comprises polymer of vinyledene chloride (PVDC).

8. **(Original)** The implant of claim **1**, wherein said pliant membrane comprises a biocompatible material.

9. **(Original)** The implant of claim **8**, wherein said biocompatible material is a polymeric film free of toxic additives.

10. **(Original)** The implant of claim **8** wherein said pliant membrane is a multilayer membrane and said biocompatible material forms an outermost layer of said multilayer membrane, said outermost layer being exposed, upon implantation of said implant, to the interior of said middle-ear chamber.

11. **(Original)** The implant of claim **1**, wherein said pliant membrane is substantially impermeable to water, gases and body fluids during protracted contact with body tissues.

12. **(Original)** The implant of claim **1** wherein said balloon contains at least one naturally occurring gas.

13. **(Original)** The implant of claim **1** wherein said balloon contains at least one non-naturally occurring gas.

14. **(Original)** The implant of claim **13**, wherein said non-naturally occurring gas is a large molecular size gas which is non-toxic and to which said pliant membrane is substantially impermeable.

15. **(Original)** The implant of claim **13**, wherein said non-naturally occurring gas is sulfur hexafluoride.

16. **(Original)** The implant of claim **1**, wherein said balloon contains a gas mixture at atmospheric pressure.

17. **(Original)** The implant of claim **1**, wherein said balloon contains a gas mixture having a pressure in the range of approximately 50 mm of water below atmospheric pressure to approximately 50 mm of water above atmospheric pressure.

18. **(Original)** The implant of claim **1**, further comprising means for self-inflating said balloon, said self-inflating means including gas at sub-atmospheric pressure effective for self-

inflation by diffusion following implantation of said implant into said middle-ear chamber.

19. **(Original)** The implant of claim 1 further comprising means for initiating self-inflation following implantation, said means for initiating self-inflation including gases at partial pressures effective to initiate self inflation.

20. **(Original)** The implant of claim 1 wherein said pliant membrane is between approximately 1 mil thick and approximately 4 mils thick.

21. **(Amended)** An implant for implantation in a middle-ear chamber, said implant comprising:

a plurality of balloons formed from a pliant membrane, said balloons configured to fit within said middle-ear chamber with at least one of said balloons at least partially in contact with the eardrum, each of said balloons having an equivalent volume selected to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.

22. **(Amended)** A surgical method for treating middle-ear hearing loss of a patient, said method comprising:

positioning a balloon in the patient's middle ear at least partially in contact with the eardrum, said synthetic balloon being formed of a thin pliant membrane of biocompatible material such that said balloon has an equivalent volume high enough to permit sound-induced motions of the eardrum, ossicles, and the round window membrane to an extent that permits the perception of sound by said patient, said pliant membrane being substantially impermeable to water and to gases during extended contact with body tissues.

23. **(Original)** A surgical method according to claim 22, wherein positioning a balloon includes positioning the balloon between the eardrum and the bone covering the cochlea.

24. **(Original)** A surgical method according to claim **22**, further comprising exposing the patient's middle ear by elevating a tympano-meatal flap before disposing said balloon in the middle ear.

25. **(Original)** The surgical method of claim **24**, further comprising securing said balloon into position with an anchor formed of resorbable packing.

26. **(Original)** The surgical method of claim **22**, further comprising positioning one or more additional balloons in the patient's middle-ear such that said additional balloons are mechanically coupled to said balloon.